DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 1, 2016

ROCHE DIAGNOSTICS CORP.
KAY TAYLOR
9115 HAGUE RD.
P.O. BOX 50457
INDIANAPOLIS IN 46250-0457

RE: K000576
Trade/Device Name: Elecsys Cortisol CalCheck
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, Reserved
Product Code: JJX
Dated: February 18, 2000
Received: February 22, 2000

Dear Ms. Taylor:

This letter corrects our substantially equivalent letter of March 21, 2000.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): N/A K000576

Device Name: Elecsys® Cortisol CalCheck

Indications For Use:

Elecsys® Cortisol CalCheck calibration verification solutions comprise three levels - low, mid, and high - each with a defined Cortisol concentration. The low solution concentration is near the lower detection limit of the assay. The middle solution is in the middle or at the clinically critical point of the measuring range. The high solution is near the upper limit of the measuring range.

The Elecsys® Cortisol CalCheck is intended for use in periodic verification of the calibration of the Elecsys® Cortisol assay.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000576

K000576

MAR 21 2000

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 576 - 3544

Contact Person: Kay A. Taylor

Date Prepared: February 18, 2000

Device Name

Proprietary name: Elecsys® Cortisol CalCheck

Common name: Calibration Verification Material

Classification name: Single (specified) analyte controls (assayed + unassayed)

Predicate device

The Elecsys® Cortisol CalCheck is substantially equivalent to the currently marketed Elecsys CalCheck TSH.

Device Description

The Elecsys® Cortisol CalCheck is a lyophilized product manufactured using a human serum base, synthetic cortisol, and preservative. The analyte is appropriately spiked into the CalCheck matrix to the correct CalCheck concentration levels.

510(k) Summary, Continued

Intended use	The Elecsys® Cortisol CalCheck is used to verify the calibration of the Elecsys® Cortisol assay.
Comparison to predicate device	The Elecsys® Cortisol CalCheck is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys® CalCheck™ TSH. Both products are intended to be used for the verification of calibration for analytes on the Elecsys® Immunoassay Analyzers.
Performance Characteristics	The Elecsys® Cortisol CalCheck was evaluated for value assignment and stability.